trauson

Trauson (China) Medical
Instrument Co.,Ltd.
9 Longmen Road,
Changzhou, Jiangsu, China
Zip Code: 213164
Tel: +86-519-86387075
Fax: +86-519-86387279

Europe Representative:
Shanghai International
Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537
Hamburg, Germany
Tel: +49-40-2513175
Fax: +49-40-255726

Bone Plates

INSTRUCTION FOR USE

CE
0123

GRAPHICAL SYMBOLS	
	Medical device
	Manufacturer
	Batch code
	Do not re-use
	Non-sterile
	Consult instructions for use
	Catalogue number
	Quantity

	Date of manufacture
	Do not use if package is damaged
	Humidity limitation
EC REP	Authorized representative in the European Community
MATL	Material
	Caution

DESCRIPTION

The Bone Plate System offers a variety of plates that are made of unalloyed titanium conforming to ISO 5832-2.

INTENDED USE

The Bone Plate system is indicated for internal fixation, stabilization and support of bone fractures as well as bone fixation after oeteotomies. Normally used together with bone screw system.

INDICATIONS FOR USE

The Bone Plate System including Locking Plates, Non-locking Plates, and Mini plates are designed to provide fixation for fractures, fusions or osteotomies. In general, these plates are indicated for fractures requiring additional stability.

Indications include:

Locking plates are indicated for:

- Osteopenic bone
- Peri-articular comminuted fractures
- Periprosthetic fractures
- Extra articular fractures
- Complete intra-articular fractures including those with associated coronal fractures
- Shaft fractures
- Supracondylar fractures
- Intra-articular fractures
- Nonunions and malunions
- Osteotomies

Non-locking plates are indicated for:

- Fractures requiring additional stability (e.g. severely comminuted fractures, etc.).
- Extra articular fractures
- Intra-articular fractures
- Complete intra-articular fractures including those with associated coronal fractures
- Metaphyseal fractures
- Supracondylar fractures
- Periprosthetic fractures
- Nonunions and malunions
- Osteotomies

Mini plates are indicated for:

- Fractures of metacarpal and phalanx.

CONTRAINDICATIONS

The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

1. Any active or suspected latent infection or marked local inflammation in or about the affected area.
2. Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
3. Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
4. Material sensitivity, documented or suspected.
5. Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
6. Patients having inadequate tissue coverage over the operative site.
7. Implant utilization that would interfere with anatomical structures or physiological performance.
8. Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
9. Other medical or surgical conditions which would preclude the potential benefit of surgery.
10. Comminuted fracture, it is difficult to fix and reset because of small and many bone sheets.

INTENDED USERS

The bone plates system is intended to be used by licensed healthcare professionals. The healthcare professionals should be fully aware of the intended use of the products and the applicable surgical techniques and should be qualified by appropriate training methods (for example, relevant surgical residency programs). Additional user groups include nurses and reprocessing staff in handling, cleaning and sterilization of the devices, where applicable.

PATIENT TARGET GROUP

The target group for the application of the bone plates system is skeletally mature patients (according to the judgment of the licensed healthcare professional) with utilization at the appropriate anatomical structures as defined in the indications.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

In many instances, adverse results may be clinically related rather than device related. This list may not include all complications caused by the surgical procedure itself.

1. Delayed union or non-union of the fracture site.
2. These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. Internal fixation devices are load sharing devices which are intended to hold fractured bone surfaces in apposition to facilitate healing. If healing is delayed or does not occur, the appliance may eventually break due to metal fatigue. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.
3. Conditions attributable to non-union, osteoporosis, osteomalicia, diabetes, inhibited revascularization and poor bone formation can cause loosening, bending, cracking, fracture of the device or premature loss of rigid fixation with the bone.
4. Improper alignment can cause a mal-union of the bone and/or bending, cracking or even breakage of the device.
5. Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
6. Early or late infection, both deep and/or superficial.
7. Deep venous thrombosis.
8. Avascular necrosis.
9. Shortening of the effected bone/fracture site.
10. Subclinical nerve damage may possibly occur as a result of the surgical trauma.
11. Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.

WARNINGS AND CAUTIONS

WARNING

1. NON-STERILE PRODUCTS: The product and the instruments to be used must be cleaned carefully in a clean environment and sterilized thoroughly with appropriate temperature and pressure before they are used.
2. IMPLANT SELECTION AND SIZING: The correct selection of the fracture fixation appliance is extremely important. Failure to use the appropriate appliance for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location,

consistent with accepted standards of internal fixation.

3. PATIENT SELECTION: Proper patient selection is critical to the success of the procedure. Only patients who satisfy the criteria set forth under the INDICATIONS section of this document AND who do not have any of the conditions set forth under the CONTRAINDICATIONS section of this document should be considered for surgery using the Bone Plate System.
4. BENDING: Bending of the Bone Plate System is not recommended. Bending will compromise the mechanical performance of the plate and may adversely affect fit and function of the screw retaining mechanisms. If bending is unavoidable, be certain to bend the plate between the screw holes. Inspect the plate for damage after bending. Do not bend the plate against the curvatures manufactured into the plate. Do not bend the plate in the vicinity of the screw holes.
5. HANDLING: Implant components should be handled and stored appropriately to protect them from unintentional damage. The surgeon should avoid introducing notches or scratches into the plate surfaces as these may induce premature failure of the component.
6. PATIENT EDUCATION: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.
7. SINGLE USE ONLY: Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Resterilization may result in damage or decreased performance.
8. COMPATIBILITY: Do not use the Bone Plate System with components of other systems. Unless stated otherwise, Trauson's devices are not to be combined with the components of another system.
9. Implant removal should be followed by adequate post-operative management to avoid fracture or refracture of the bone.
10. For optimal results, the same type of instruments used for implantation should be used for implant removal.
11. Trauson does not and cannot warrant the use of instruments nor any of the component

parts upon which repairs have been made or attempted except as performed by Trauson or an authorized Trauson repair representative. The use of an Instrument for tasks other than those for which they are intended may result in damaged/broken instruments and/or patient injury.

12. If there is any doubt or uncertainty concerning the proper use of instruments please contact Trauson Customer Service. Any available operation brochure will be provided upon request.

PREOPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. Unless stated otherwise, the device is not to be combined with the components of another system.
5. All parts should be cleaned and sterilized before use.

CAUTION

1. Before using this product, the users must read carefully Surgical Technique published by Trauson and are skilled in the operation process of this product.
2. It is not recommended to use Trauson products together with other brands, as it is not verified or validated.

PRE-OPERATIVE

1. The implant is for single use only.
2. Ensure that all components needed for the operation are available in the operation theatre.
3. Inspection is recommended prior to surgery to determine if implants have been damaged during storage.
4. While rare, intra-operative fracture or breakage of instruments can occur. Instruments which have experienced excessive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage prior to surgery.

INTRA-OPERATIVE

1. Avoid surface damage of implants.
2. Discard all damaged or mishandled implants.
3. Contouring or bending of an implant should be avoided where possible, because it may reduce its fatigue strength and can cause failure under load. If contouring is necessary, allowed by design or prescribed by Trauson, the physician should avoid sharp bends, reverse bends or bending the device at a screw hole. Such action must be performed with Trauson instruments and in accordance with the specified procedures (see

operative technique manual).

4. During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, required for precise positioning and fixing is secure.
5. After the procedure check the proper positioning of all implants using the image intensifier.
6. Do not use components of the Trauson product systems in conjunction with components from any other manufacturer's system unless otherwise specified (see operative technique manual).

POST-OPERATIVE

1. Post-operative patient activity: These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason post-operative instructions and warnings to patients are extremely important. External immobilization (e.g. bracing or casting) may be employed until X-rays or other procedures confirm adequate bone consolidation.
2. The implant is a short-term implant. In the event of a delay in bone consolidation, or if such consolidation does not take place, or if explantation is not carried out, complications may occur, for example fracture or loosening of the implant or instability of the implant system. Regular post-operative examinations (e.g. X-ray checks) are advisable.
3. The risk of post-operative complication (e.g. failure of an implant) is higher if patients are obese and/or cannot follow the recommendations of the physician because of any mental or neuromuscular disorder. For this reason those patients must have additional post-operative follow-up.
4. Implant removal should be followed by adequate post-operative management to avoid fracture or refracture of the bone.

INFORMING THE PATIENT

The implantation affects the patient's ability to carry loads and her/his mobility and general living circumstances. For this reason, the surgeon must counsel each patient individually on correct behavior and activity after the implantation.

The surgeon must warn patient that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity, trauma, mal-union or non-union and that the device has a finite expected service life and may need to be removed at some time in the future.

Explain the need to report unusual changes in the implantation area as well as falls or accidents even if the device or the site of operation did not appear to be harmed at the time.

Explain also the need to appear for the postoperative examinations (e.g. X-ray checks) and for the possible explantation of the implant.

MAGNETIC RESONANCE IMAGING (MRI) INFORMATION

The bone plate system has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment and has not been tested for heating or migration in the MR

environment unless specified otherwise on the product labels and/or in the respective operative technique.

CLINICAL BENEFITS

Locking plates were designed to provide a solution for indications including comminuted fractures and osteopenic bone. Locking plates can provide a construct that resists angular varus deformity, as well as prevents primary and secondary loss of reduction.

The shape, design and the material properties of the Non-locking plates take into account the demands from surgeons for high fatigue strength, optimized load transfer and ease-of-use instruments.

Mini plates were low profile to reduce soft tissue irritation and pre-contoured for anatomic fit. The broad range of Mini plates were available to address various fracture patterns.

PERFORMANCE CHARACTERISTICS

When used according to the manufacturer's instructions for use and labelling, the bone plates system is intended to support bone consolidation by providing stabilization of bones and bone fragments, to be used with bone screws together.

PACKAGING

Packages for each of the components should be intact upon receipt. All implant and instrument sets should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to Trauson.

CLEANING AND DECONTAMINATION

Products delivered in non-sterile condition, must be cleaned, disinfected, and sterilized prior to use. For cleaning and sterilization, remove the product from its packaging before cleaning, disinfecting and sterilizing the product. A suitable cleaning, disinfection and sterilization process must be applied by the user. Only pH-neutral cleaning agents should be used. The preparation instructions of the respective cleaning and disinfection agent manufacturer must be considered.

All instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

All instrument moving parts should be well lubricated. Be careful to use surgical lubricants and not industrial oils.

Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and must not be used.

STERILIZATION

The following sterilization process parameters are validated by Trauson and recommended

for sterilization:

Method	Moist heat sterilization according to ISO 17665
Cycle	Saturated steam with fractional forced air removal
Temperature	132-137°C (270-277°F)
Exposure Time	4 minutes (minimum)
Drying Time	30 minutes (minimum, in chamber)

Additionally, the method of sterilization utilized by end users should be validated, as suggested by Trauson.

NOTIFICATION

Please inform the manufacturer and the national authority, if a product related incident has occurred while using this device.

TRANSPORTATION AND STORAGE CONDITIONS

The relative humidity of transportation and storage is no more than 80%. Keep products in draughty room without corrosive gas.

DISPOSAL

The hospitals should follow the national regulations in force for medical waste disposal. Contaminated units should be decontaminated before they are discarded.

INFORMATION

To obtain Operation Technique or should any information regarding the products or their uses be required, please contact your local representative or Trauson directly at +86-519-86387075. You may also email: info@trauson.com .